

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 16

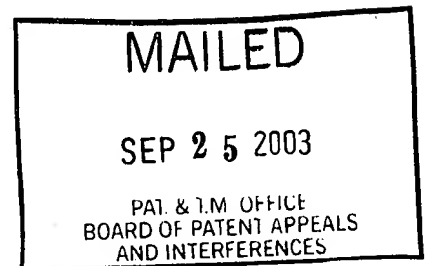
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID M. FLYNN, STUART R. CHASTAIN,
STEVE HAHN, and JUNE M. ZYTKOVICZ

Appeal No. 2001-1196
Application No. 09/139,155

ON BRIEF



Before THOMAS, RUGGIERO, and GROSS, **Administrative Patent Judges**.
GROSS, **Administrative Patent Judge**.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 through 15, which are all of the claims pending in this application.

Appellants' invention relates to an electrical lead structure for connection to an implantable medical device, such as a pacemaker. Claim 1 is illustrative of the claimed invention, and it reads as follows:

1. A lead capable of electrical and mechanical coupling to both a port of an implantable medical device's header assembly and to another lead, said lead comprising:

- (a) an elongated, main body portion having a proximal and distal end;
- (b) at least one terminal connector attached to the proximal end of the main body and adapted for coupling the lead to a header assembly of a medical device;
- (c) at least one electrode embodied within the main body portion;
- (d) at least one conductor corresponding with each electrode and electrically insulated, wherein a distal end of each conductor is attached to each corresponding electrode and a proximal end of each conductor is attached to at least one corresponding terminal connector;
- (e) an adapting member extending from the lead having a port adaptable for sealably receiving a terminal connector of a second lead, said port having an electrically conductive terminal block positioned within said port, wherein a jumper wire is electrically coupled to the terminal block and the conductors of the main body of the lead.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Stutz, Jr. (Stutz)	5,413,595	May 09, 1995
Fain et al. (Fain)	5,679,026	Oct. 21, 1997

Claims 1 through 15 stand rejected under 35 U.S.C. § 103 as being unpatentable over Stutz in view of Fain.

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Reference is made to the Examiner's Answer (Paper No. 13, mailed September 14, 2000) for the examiner's complete reasoning in support of the rejections, and to appellants' Brief (Paper No. 11, filed July 31, 2000) and Reply Brief (Paper No. 14, filed November 14, 2000) for appellants' arguments thereagainst.

OPINION

As a preliminary matter, we note that appellants indicate on pages 3-4 of the Brief that the claims should stand or fall separately. However, the only claims argued separately in the Brief are claims 2, 4, 5, 11, and 12, for which appellants argue a rejection that has not been applied against the claims.

37 C.F.R. § 1.192(7) states:

For each ground of rejection which appellant contests and which applies to a group of two or more claims, the Board shall select a single claim from the group and shall decide the appeal as to the ground of rejection on the basis of that claim alone unless a statement is included that the claims of the group do not stand or fall together **and, in the argument under paragraph (c)(8) of this section, appellant explains why the claims of the group are believed to be separately patentable.** . . . (Emphasis ours)

We note that in the Reply Brief (at page 10), appellants do present arguments for some of the dependent claims not argued in the Brief. However, 37 C.F.R. § 1.192(a) states that "[a]ny arguments or authorities not included in the brief will be

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refused consideration by the Board of Patent Appeals and Interferences, unless good cause is shown." **See also, In re Berger**, 61 USPQ2d 1523, 1529 (Fed. Cir. 2002) and **Interactive Gift Express, Inc. v. Compuserve**, 256 F.3d 1323, 1344, 59 USPQ2d 1401, 1417 (Fed. Cir. 2001), in which the Federal Circuit held that issues not raised in the Brief are waived. Under current practice, the examiner is unable to respond to arguments made in the Reply Brief and would thereby be prejudiced if we were to consider arguments raised for the first time in the Reply Brief. Accordingly, we will not consider the arguments raised in the Reply Brief for the dependent claims and will treat the claims as a single group, with claim 1 as representative.

We have carefully considered the claims, the applied prior art references, and the respective positions articulated by appellants and the examiner. As a consequence of our review, we will affirm the obviousness rejection of claims 1 through 3, 6 through 10, and 13 through 15 and reverse the obviousness rejection of claims 4, 5, 11, and 12. We also will enter a new ground of rejection as to claims 4, 5, 11, and 12.

Appellants argue (Brief, page 5) that the references fail to teach or suggest the claimed invention. Specifically, appellants assert that "Stutz does not even include an adapting member" and

"does not describe electrically connecting two leads to a single port." Appellants conclude (Brief, page 6) that Stutz fails to teach providing a lead "with an adapter as part of the lead." We agree that Stutz does not disclose an adapting member nor connecting two leads to a single port. However, the rejection is over Stutz in view of Fain, and the examiner applies Fain for these two limitations. As to a lead with an adapter as part of the lead, claim 1 is not so limited. Claim 1 requires that the adapter extend from the lead, but that differs from being a part of the lead. The adapter can extend from the lead without being formed as a part of the lead.

Similarly, appellants argue (Brief, page 6) that Fain fails to suggest a lead "having an adapting member formed as part of the lead." As explained *supra*, the claims are not so limited. Appellants also argue (Brief, page 6) that Fain fails to describe connecting multiple leads to a single port, as "Fain requires the same number of ports as number of leads used." We disagree. Fain discloses (column 8, lines 40-60) that connector blocks for leads 42 and 44 are both electrically connected to lead connector 50, which in turn connects to the header, and connector 51 serves as a dummy lead connector, since no connector blocks are connected thereto.

Appellants continue (Brief, page 7) that there is no teaching or suggestion to combine the devices of Stutz and Fain. Yet, Fain teaches (column 1, lines 5-11) that the purpose of the disclosed adapter is "to provide a different lead connector port configuration than is provided by the header of the implantable cardiac stimulation device." The different configurations include both different size leads and also different numbers of leads. Accordingly, Fain clearly provides motivation to combine the adapter of Fain with the lead of Stutz. In addition, notwithstanding appellants' argument to the contrary (Brief, page 9) the accommodation of a different number of leads and ports is the same purpose and function disclosed by appellants.

Appellants further contend (Brief, page 7) that the combination does not result in the claimed invention. More specifically, appellants assert that "[a] lead adapter integrated into a lead body was neither suggested or taught by Stutz or Fain." Appellants continue (Brief, page 8) that it would not have been obvious to combine Fain's adapter and Stutz's lead "into a unitary lead and adapter." Likewise, appellants state (Brief, page 8) that neither reference teaches forming the adapting member "as part of the lead." However, claim 1 merely requires that the adapting member "extend from" the lead, not be

a part of or be integrated with the lead. Appellants (Reply Brief, page 2) apparently want us to read "extending from" as "unitarily formed," but the two phrases are different in scope and are not interchangeable. If two people extend their arms and hold hands, one arm extends from the other, but they clearly are not unitarily formed.

The examiner (Answer, page 5), for reasons unbeknownst to us, asserts that a one piece construction for the lead and adapter would have been an obvious engineering choice and cites ***In re Larson*** as support thereof. Appellants then argue (Brief, page 8, and Reply Brief, pages 5-7) that reliance on ***Larson*** is inappropriate. As explained supra, a one piece construction is not recited in the claims, and, therefore, all arguments related thereto are not pertinent.

Appellants also argue (Brief, pages 9-10, and Reply Brief, pages 7-8) that the examiner has failed to consider the problem solved, i.e., the need to eliminate a separate adapter and reduce the number of seals necessary when connecting multiple leads to a single port on a header. However, nothing in appellants' claims addresses these problems. The ***claimed*** invention is not limited to a unitary construction and thereby does not address the need

to eliminate a separate adapter. Similarly, nothing in the **claimed** invention requires a reduction in the number of seals. Appellants argue (Reply Brief, page 8) that Fain's use of a dummy lead teaches away from appellants' invention, since Fain requires an extra seal, but appellants' claims do not preclude the use of a dummy lead and an extra seal. Consequently, we will sustain the rejection of representative claim 1 and the claims grouped therewith, claims 2, 3, 6 through 10, and 13 through 15.

Appellants (Brief, pages 10-11) argue against the obviousness of claims 2, 4, 5, 11, and 12 over Fain alone. Appellants (Reply Brief, page 9) contend that such rejections over Fain alone appear in the Final Rejection dated February 28, 2000. We find no such rejection. The examiner has consistently rejected all of the claims over the combination of Stutz and Fain (see the Final Rejection, page 2). The portion of the Final Rejection referenced by appellants discuss sections of Fain as part of the combination of Stutz and Fain, not as a separate rejection over Fain alone. Therefore, all arguments addressing Fain alone are considered moot.

Regarding claims 4, 5, 11, and 12, although the examiner includes these claims in the statement of the rejection, he makes no reference to these claims in the explanation of the rejection

and even admits (Answer, page 9) that the prior art fails to teach an aperture extending through the adapter as claimed. Accordingly, the examiner has implicitly withdrawn the rejection of claims 4, 5, 11, and 12. Therefore, we must reverse the rejection of claims 4, 5, 11, and 12.

However, as we find that the references do teach or suggest the limitation of claims 4, 5, 11, and 12, we hereby reinstate the rejection of claims 4, 5, 11, and 12 under 35 U.S.C. § 103 over Stutz in view of Fain **via** a new ground of rejection under 37 C.F.R. § 1.196(b). More specifically, each of claims 4, 5, 11, and 12 recites that the adapter "has an aperture extending therethrough such that the aperture aligns with a header port when the lead is coupled to the header assembly." Fain shows (or at least suggests) in Figures 4 and 5 that the aperture in the adapter through which lead 50 is inserted aligns with the corresponding port in the header. Accordingly, the combination of Fain's adapter with Stutz's lead would have rendered obvious the limitation of claims 4, 5, 11, and 12.

Appellants argue (Brief, page 9) that the limitation of claims 4, 5, 11, and 12 of "an aperture extending through the adapter so that a lead could connect directly to a port on the header through the lead adapter" is missing from Fain. However,

the claims do not recite a direct connection, as argued. The claims merely require that the aperture be aligned with the header port. When the lead is inserted into the adapter and connected to the header, the aperture through which the lead is inserted will be aligned with, or in line with, the header port. Further, Figure 5 of Fain appears to have the adapter abutted with the header assembly such that the aperture and the header port are aligned as aligned for direct connection. Therefore, claims 4, 5, 11, and 12 would have been obvious over Stutz in view of Fain.

CONCLUSION

The decision of the examiner rejecting claims 1 through 15 under 35 U.S.C. § 103 is affirmed as to claims 1 through 3, 6 through 10, and 13 through 15 and reversed as to claims 4, 5, 11, and 12. In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of rejection of claims 4, 5, 11, and 12 under 35 U.S.C. § 103 pursuant to 37 C.F.R. § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 C.F.R. § 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

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Regarding any affirmed rejection, 37 C.F.R. § 1.197(b) provides:

(b) Appellants may file a single request for rehearing within two months from the date of the original decision

37 C.F.R. § 1.196(b) also provides that the appellants, **WITHIN TWO MONTHS FROM THE DATE OF THE DECISION**, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 C.F.R. § 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

Should the appellants elect to prosecute further before the Primary Examiner pursuant to 37 C.F.R. § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

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If the appellants elect prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for reconsideration thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART
37 C.F.R. § ~~1.196~~(b)

JAMES D. THOMAS
Administrative Patent Judge

Joseph F. Ruggiero
JOSEPH F. RUGGIERO
Administrative Patent Judge

Anita Pellman Gross
ANITA PELLMAN GROSS
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